K010032

OCT 1 7 2001

Nucletron

NUCLETRON B.V.
Waardgelder 1 3905 TH Veenendaal
P.O.Box 930 3900 AX Veenendaal
The Netherlands
Phone +31 318 557133
Fax +31 318 550485

Department of Health and Human Services
Center of Device and Radiological Health
Office of Device Evaluation
Pre-Market Notification Section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

a. Submitter of 510(k)

Company name:	Nucletron Corporation
Registration #	1121753
Address:	7080 Columbia Gateway Drive Columbia, MD 21046-2133
Contact Person:	Robert Applebaum, C.H.P., R.S.O. Director Assurance & Regulatory Affairs
Phone:.	410-312-4100
Fax:	410-312-4197

b. Device Name:

Trade/Proprietary Name:	**seedSelectron**
Common/Usual Name:	Seed loading and insertion Device
Classification Name:	Remote controlled radionuclide applicator system 21 CFR 892.5700, Class II.

c. Legally Marketed Predicate Device(s)

Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

The following devices listed below represent the predicate devices used for substantial equivalence. These devices are currently marketed products with current premarket notification numbers.

Device	Premarket #
Nucletron MicroSelectron	**K953946**
Mick-Applicator Quick Seeder	**K913293**

d. Description

The **seedSelectron** is assembled under sterile conditions in the operating theatre. Following trans-rectal US guided trans-perineal needle implantation of the prostate and treatment planning, the operator is programming the loading configuration for each needle , or the loading configuration for the needles is transferred automatically from the planning system to the **seedSelectron**. After having the loading configured, the **seedSelectron** is attached to the SU, fixed at the operating table or at a floor stand. The physician selects the desired sequence from treatment prescription and connects the **seedSelectron** according this sequence to the needles. With the connection of the **seedSelectron** a hook is placed at the distal part of the needle connector. The operator starts the loading process. The drive wire automatically will compose the seed/spacer into the composing tube. The train will be pushed from the composing tube into the distal position of the needle. After insertion of the train into the needle, the drive cable stays in place inside the needle. The slider is moved in the proximal position and automatically retracts the needle over the seed train

The device will be connected to the next position and the procedure of loading and needle retraction starts again.

The System provides rapid patient loading with minimal radiation exposure to the personnel.

Materials with Patient Contact

Component of the device	Patient Contact	Material	Current use in Marketed Products
Needles	Yes	AISI 316L	Nucletron Interstitial Set Part # 110.109
Spacers	Yes	Poly(L-lactide-co-D,L-lactide) 70:30	1.Meniscal (Arthrex, Inc) 2.Protego (MacroPore, Inc) 3. Polypin (Biovision)

e. Intended Use

The **seedSelectron** is intended for use in the treatment of cancer with radioactive sources in close proximity to or within the tumor.

The **seedSelectron** is intended for treatment of prostate cancer with the Nucletron **SelectSeeds I-125** or with seeds from other manufacturer.

These sources are commonly used to treat superficial, intra-abdominal, and intrathoracic tumors, in particular tumors of the prostate. Other indications include tumors of the head, neck, lung and pancreas. They may be used alone, or in combination with external beam radiation.

It provides the therapist with a semi-automatic tool to compose the configuration of radioactive seeds and spacer and deliver the radioactive sources to the treatment site in a safe, accurate and reliable manner. This device is intended to compose a train of radioactive seeds and spacers under radiation protection and loads the train into needles implanted into the prostate.

- The **seedSelectron** is a motorised device.

Contraindications

Treatment of tumours in a generally bad or ulcerated state is not recommended.

Adverse reactions

Since the therapeutic effect is achieved by radioactive radiation, radiation damage can occur in healthy tissue.

Possible adverse reactions associated with implant usage in the prostate have been reported to include irritative uropathy symptoms including increased urinary frequency, urgency and obstruction. Complications have also included cystitis, urethritis, superficial urethral necrosis, hematuria, stricture and contracture, impotence, incontinence and proctitis.

e. Summary of technological considerations

The Nucletron **seedSelectron** is substantially equivalent to the predicate devices. It combines the functionality, components and design of the predicate devices. In contrast to predicate devices some **seedSelectron** components are provided sterile. .

D. Kindlein

Dec. 11. 2000

Name: Johann Kindlein
Title Product Manager
Nucletron BV
Veenendaal
Netherlands

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 7 2001

Ms. Lisa Cole Dimmick
Director of Regulatory Affairs
Nucletron Corporation
7080 Columbia Gateway Drive
COLUMBIA MD 21046-2133

Re: K010032
Trade/Device Name: Seed Selectron Model V.1.0 Brachytherapy Planning System
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radio-nuclide Applicator System
Regulatory Class: II
Product Code: 90 JAQ
Dated: September 10, 2001
Received: September 12, 2001

Dear Ms. Dimmick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K010032

Premarket Notification
Nucletron seedSelectron
Date : December 11 , 2000

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Department of Health and Human Services
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Indication for Use Statement

Device Name: seedSelectron

Indications

The **seedSelectron** is intended for treatment of prostate cancer with the Nucletron **SelectSeeds I-125 (separate 510(k) filing) or with seeds from other manufacturer.**

These sources are commonly used to treat superficial, intra-abdominal, and intrathoracic tumors, in particular tumors of the prostate. Other indications include tumors of the head, neck, lung and pancreas. They may be used alone, or in combination with external beam radiation.

It provides the therapist with a semi-automatic tool to compose the configuration of radioactive seeds and spacer and deliver the radioactive sources to the treatment site in a safe, accurate and reliable manner. This device is intended to compose a train of radioactive seeds and spacers under radiation protection and loads the train into needles implanted into the prostate.

- The **seedSelectron** is a motorised device.
- The spacer cartridge is disposable and delivered to the customer sterile packed with spacers.
- The drive system and slider are assembled and are for single use only, because of blood contamination through.
- Connecting tube for the needle is for single use only.

J. Kindlein Dec. 11. 2000

Name Johann Kindlein
Title Product Manager
Nucletron BV
Veenendaal
Netherlands

Date

Nancy C Brogdon

Division Sign-Off)
Division of Reproductive, Abdominal,
Radiological Devices
(510(k) Number K010032

Prescription Use ✓